UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA N.V. and JANSSEN PHARMACEUTICA PRODUCTS, L.P., Plaintiffs and Counterclaim Defendants, v. MYLAN PHARMACEUTICALS INC., Defendant and Counterclaim Plaintiff.	)	Civ. Action No. 2:03-CV-06220 Judge John C. Lifland Magistrate Judge Mark Falk
JANSSEN PHARMACEUTICA N.V. and JANSSEN PHARMACEUTICA PRODUCTS, L.P., Plaintiffs and Counterclaim Defendants, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants and Counterclaim Plaintiffs.	)	Civ. Action No. 2:03-CV-06185 Civ. Action No. 2:05-CV-00884 Judge John C. Lifland Magistrate Judge Mark Falk ***DOCUMENT ELECTRONICALLY FILED***

DEFENDANTS' REPLY TO PLAINTIFFS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. INTRODUCTION

Defendants again submit that a clear and convincing case of *prima facie* obviousness with respect to Compound 11 was presented at trial. The Defendants' obviousness case is a simple one, based upon the existence of Janssen's own prior art compound, Pirenperone, which when modified at a single structural location, in a manner motivated by the prior art, results in Compound 11.

Defendants' case of obviousness is well founded upon the Federal Circuit's *en banc* decision styled *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc), which sets forth the unequivocal standard to be applied in this case:

> Structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness.

See id., citing In re Mayne, 104 F.3d 1339, 1342 (Fed. Cir. 1997).

In their post-trial brief, Defendants set forth the following table that summarizes the properties that were known to those of ordinary skill in the art in the early 1980s to be desired in an antipsychotic drug.

Properties Known to Those of Ordinary Skill in the Art in the Early 1980s to be Desired in an Antipsychotic Drug	
	Pirenperone
1. Dopamine Receptor Antagonist	√
2. Passes Blood-Brain Barrier	√
3. Safe to Use in Humans	√
4. Does Not Cause EPS	√
5. Serotonin Receptor Antagonist	√
6. Long Duration of Action	⊗

In the table, Defendants also indicated that Janssen's prior art compound, Pirenperone, satisfied all but one of those properties. Janssen, in its Findings of Fact and Conclusions of Law ("*JFF/CL*"), attempts to challenge points 4 and 6 in the table, arguing that Pirenperone caused extrapyramidal symptoms ("EPS") and that Pirenperone did not have a short duration of action. Janssen is, of course, wrong on both counts and Janssen's scientists themselves have admitted as much. These points are discussed *infra* at *Sections V.C. & IV., respectively.*

Janssen also attempts to add a seventh criterion to the table—"anticholinergic activity." This issue is nothing more than an unnecessary diversion of the Court's attention. As the Court well knows, Janssen spent an extraordinary amount of time at trial trying to support their "anticholinergic" theory. In Paragraphs 111 through 153 of its proposed findings, Janssen extensively argues that one of skill in the art in the early 1980s would have been looking for a drug with anticholinergic properties in order to develop an antipsychotic with low or no EPS, and that Pirenperone would not have been a

logical starting point because it did not exhibit anticholinergic properties. Janssen also throws into its argument that, in addition to the anticholinergic theory, other theories existed which allegedly described ways of avoiding EPS. The ultimate goal of Janssen's anticholinergic theory is to depict the combination dopamine and serotonin antagonism theory for antipsychotic development (*i.e.*, the very theory adopted by Janssen and taught to others of skill in the art in the late 1970s to early 1980s time frame) as nothing more than "quackery." *See Section V.C., infra.*

However, stepping back for a moment from Janssen's argument, one reaches the simple conclusion that even if Janssen is correct that a majority of researchers were looking for compounds with anticholinergic activity to avoid EPS, this in and of itself would have been irrelevant to one of ordinary skill in the art. This is because one of ordinary skill in the art in the early 1980s had as an ultimate goal the development of an antipsychotic with low EPS, not a goal of developing a drug having anticholinergic activity. Anticholinergic activity was only one theoretical *means* of achieving the goal of low EPS. Since it was known that Pirenperone did not induce EPS in humans, how and why Pirenperone achieved the goal of having low EPS would have been irrelevant to one of ordinary skill in the art. This is because the goal of inducing low EPS was already achieved in Pirenperone, and whether it also had anticholinergic activity was irrelevant.

Of course, as Defendants established at trial, Pirenperone appears to achieve low EPS due to its combined dopamine and serotonin antagonism activity (in

accord with Janssen's own theory). Defendants' position regarding this is further discussed *infra* at *Section V.C.*

Janssen's next attempt to disparage Pirenperone as a logical starting point for developing an antipsychotic was to argue that Pirenperone simply had no antipsychotic activity. This is an untenable position, as Janssen's own scientists have always characterized Pirenperone as an antipsychotic. Janssen did not prove otherwise at trial. This issue is discussed *infra* at *Section V.A.*

Finally, Janssen argues that there were many other compounds that could have been used as a starting point by one of skill in the art other than Pirenperone. As discussed *infra* at *Section II.A.2*, Janssen's argument is legally irrelevant.

Turning to the motivation to modify Pirenperone, as this Court is well aware, Defendants' obviousness case is based on the fact that (1) once one skilled in the art was aware of Pirenperone's short half-life, (2) one would have recognized that the likely cause of that short half-life was the keto group in Pirenperone, and (3) would have been motivated to substitute the keto group with a benzisoxazole to provide the desired increase in half-life, (4) with a reasonable expectation that Pirenperone's antipsychotic activity would have been maintained. Again, Defendants proved each of these points at trial through clear and convincing evidence, and Janssen's responses to each of these points either ignores or totally mischaracterizes the trial record, as discussed *infra* at *Section IV.*

With respect to secondary considerations of nonobviousness, there are none that are relevant to Compound 11 since that compound never found its way out of Janssen's laboratory. There is *no* rebuttal to the fact that Risperidone has properties that have never been associated with Compound 11. Coupled with the structural difference between Compound 11 and Risperidone, these facts totally defeat any attempt by Janssen to use the commercial success of Risperidone to bolster the "nonobviousness" of the otherwise unpatentable Compound 11. Secondary considerations are discussed further *infra* at *Section VI.*

Janssen alleges that Mylan abandoned its inequitable conduct case at trial. Nothing could be further from the truth. As the Court knows, Mylan's inequitable conduct case is based upon the documentary evidence, coupled with the deposition testimony of the inventor, Mr. Kennis, and others which is part of the trial record through designations. Additionally, Mylan submits that the trial testimony of Dr. Dellenbaugh——that he did not know about the properties of Pirenperone as a dopamine antagonist——was simply not credible. The Mylan inequitable conduct case is discussed further *infra* at Section VII.

II. DEFENDANTS HAVE SET FORTH THE PROPER OBVIOUSNESS STANDARD—A STANDARD ADOPTED BY THE FEDERAL CIRCUIT IN AN *EN BANC* DECISION

Defendants have shown structural similarity between the '663 patent claims (Compound 11) and the prior art (Pirenperone), and have also identified the

motivation in the prior art for one skilled in the art to modify Pirenperone, thereby yielding Compound 11. Thus, Defendants have established a *prima facie* case of obviousness. *See, e.g., Section III. of Defendants' FF/CL; Section II. of Defendants' Post-Trial Brief.*

Janssen's cry of hindsight is extinguished by a showing of motivation. *See Medichem, S.A. v. Rolabo, S.L.,* 437 F.3d 1157, 1164 (Fed. Cir. 2006) (It is the requirement of a motivation to combine that "stands as a critical safeguard against the application of hindsight.") Janssen's assertion that Defendants' obviousness case is based on hindsight is not only unsupported, but is further fatally undermined by Defendants' identification of motivation in the prior art to select and modify Pirenperone, yielding Compound 11. Nothing more is required by law. *See In re Dillon,* 919 F.2d at 692.

A. DEFENDANTS' PROOFS ARE LEGALLY SUFFICIENT TO ESTABLISH PIRENPERONE AS WITHIN THE SCOPE AND CONTENT OF THE PRIOR ART

1. The Parties Agree That *Graham* Controls

The parties agree that the *Graham* factors control this Court's obviousness analysis. *See Graham v. John Deere & Co.,* 383 U.S. 1 (1966). However, there appears to be disagreement as to the proper legal standard for one of the *Graham* factors—determining the scope and content of the prior art—and whether there exists evidence sufficient to conclude that Pirenperone is within the scope and

content of the prior art. Under the case law set forth in Defendants' post-trial submissions (which is not repeated here), there is no doubt that Pirenperone is within the scope and content of the prior art. *See Section III.B.1. and III.B.2.b. of Defendants' FF/CL.*

2. Janssen's Reliance on *Yamanouchi* is Misplaced; Identification of a "Lead Compound" is Not a Predicate to Obviousness

a. Summary of *Yamanouchi* and Its Progeny

Janssen's rebuttal appears to be based solely on the *Yamanouchi* case and its progeny which, in Janssen's words, require the presentation of a "scientific reason why one of ordinary skill would chose to begin their research with Pirenperone." According to Janssen, skilled persons typically begin their research project by selecting a "lead compound," ultimately concluding, of course, that Pirenperone would not have been an appropriate "lead compound." *See JFF/CL ¶ 74.*

Janssen's assertion that a single "lead compound" must be identified by Defendants is based on an erroneous analysis of the relevant case law. None of the cases cited by Janssen, *Yamanouchi* included, mandate the identification of a "lead compound" as a predicate to an obviousness finding. Nor do these cases preclude the identification of a plurality of "lead compounds." Although not pointed out by Janssen, these cases follow the same legal standard promoted by Defendants—*In re Dillon* and *Graham*.

The failure of proof in the cases cited by Janssen is the same—the challengers failed to identify a reason for selecting the compound they were using as a starting point in their obviousness analysis. The requirement of a "reason" arises from the first *Graham* factor (*i.e.*, the compound must be within the scope and content of the prior art), and the term "lead compound" is simply a label taken from the pharmaceutical industry that is applied to a compound that meets this requirement, *i.e.*, a compound that is "within the scope and content of the prior art" may be referred to as a "lead compound." *See JFF/CL ¶ 74 (skilled persons "typically begin their research [i.e., in industry] by selecting a lead compound").* Compounds that are not within the scope and content of the prior art cannot be so-called "lead compounds," and an allegation of obviousness based on such compounds must fail, as it did in the cases cited by Janssen.

Here, Defendants provided prior art-based reasons (as required by *Graham*) which explain why Pirenperone is within the scope and content of the prior art. Defendants did so by showing which properties one skilled in the art in the early 1980s was looking for in an antipsychotic, and how Pirenperone met those desired properties. *See Table (p. 2, supra); Section III.B.1. & III.B.2.b. of Defendants' FF/CL.* The case law requires no more.

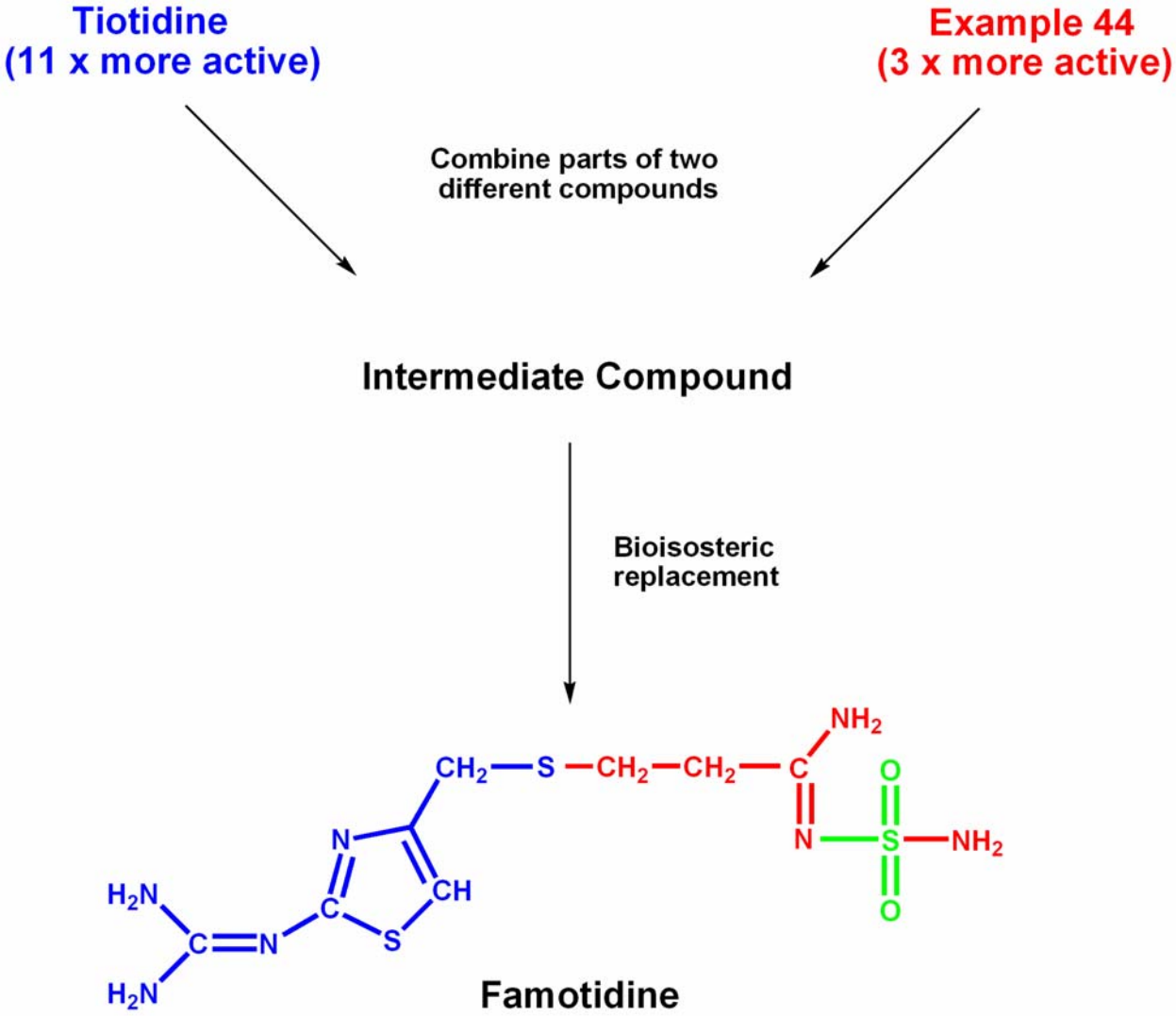
b. The *Yamanouchi* Case Does Not Compel a Conclusion of Nonobviousness

In contrast to Janssen's characterization, the Federal Circuit describes the validity case in *Yamanouchi* as follows: "[a]t the heart of this validity dispute is whether one of skill in this art would have found motivation to combine pieces from one compound in a prior art patent with a piece of another compound in the second prior art patent," and then perform further manipulations of the resulting intermediate to provide the claimed compound. *See Yamanouchi Pharm. Co., Ltd. v. Danbury Pharm., Inc.*, 231 F.3d 1339, 1343 (Fed. Cir. 2000).

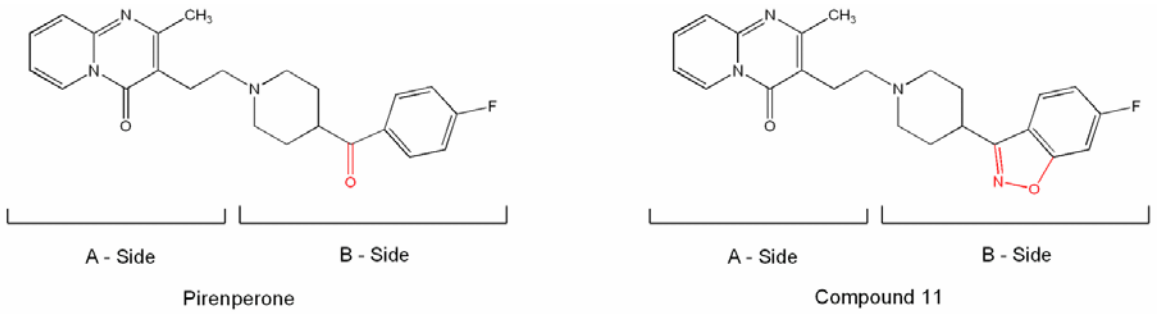
Indeed, the use of the term "lead compound" in *Yamanouchi* is clearly (and only) attributable to the defendant Danbury, who uses this term as shorthand for a compound that is within the scope of content of the prior art. *Id.* at 1343-44. We know this because the Federal Circuit refers to the compounds as "prior art references" throughout the opinion, *e.g.*, "the district court discerned that Danbury had not proven any motivation to combine *prior art references* to produce the claimed invention," and references the *Graham* factors. *Id.* at 1342 & 1343 (emphasis added). The mention of "lead compound" only begins when the Federal Circuit discusses how defendant Danbury explained its obviousness case to the Court. *See, e.g., id.* at 1343. Read carefully and properly, *Yamanouchi* falls far short of Janssen's assertion that the Federal Circuit "mandates" the identification

of a lead compound as a predicate to an obviousness analysis; indeed, there is no language in *Yamanouchi* which mandates this approach at all.

Moreover, the present case is factually distinguishable from *Yamanouchi*. Here, Defendants, unlike defendant Danbury, are not suggesting ripping apart two separate compounds located in two separate patents (Figs. 3 and 4 of *Yamanouchi*), joining parts of each disjoined compound to create an intermediate compound (Fig. 5 of *Yamanouchi*), and then modifying that intermediate compound to provide the claimed compound. *Id.* at 1344. See the following illustration, which shows the numerous manipulations of the prior art alleged by Danbury to render the claims obvious).



On the contrary, and as shown below, Defendants have demonstrated a *prima facie* case of obviousness—a single, straight-forward change to one compound (Pirenperone) to provide the claimed subject matter of the '663 patent (*i.e.*, Compound 11), and the motivation for one skilled in the art to do so:



Even if one assumes that Janssen's theory (JFF/CL ¶ 74) has merit, there was every "scientific reason" in the world for one of ordinary skill in the art in the early 1980s seeking an antipsychotic to select Pirenperone for development as an antipsychotic, *e.g.*, it had dopamine antagonism, passed the blood-brain barrier, had low EPS, had been safely used in the clinic (*i.e.,* in humans), and had serotonin antagonism. *See, e.g., Sections III.B.1. and III.B.2.b.i.-v. of Defendants' FF/CL*. Indeed, it is only by mischaracterizing Pirenperone's properties that Janssen is able to argue that Pirenperone—even under Janssen's own erroneous legal standard—would not have been suitable to use as a "lead compound."

c. Janssen's "Other" Pharmaceutical Cases Provide No Further Guidance

Janssen relies on several other pharmaceutical cases in support of its argument, but each is readily distinguishable from the present case on its facts. For example, Janssen argues that one such case, involving the compound Olanzapine (Zyprexa®) (*JFF/CL ¶ 78*), is "virtually identical to this one." *See Eli Lilly & Co. v. Zenith Goldline Pharms.*, 2001 WL 1397304 (S.D. Ind., Oct. 29, 2001). However, the facts show that this case is not even close.

Unlike the '663 patent, the claims in the Olanzapine patent include a claim directed solely to this single active ingredient. *Id.* at 851-52 ("Claim 1 claims the compound olanzapine"). Here, of course, the '663 patent does not include even one claim directed solely to Risperidone. Thus, in the present case, a conclusion of obviousness relative to Compound 11 renders the claims invalid—despite that fact that Risperidone may not be obvious.

Further, the *Eli Lilly* court concluded as part of its obviousness analysis that the prior art taught away from the selection of unfluorinated compounds such as the '222 compound (*i.e.*, a compound relied on by defendants as rendering the claims obvious). For example, the court in *Eli Lilly* found there was no biological data supporting use of the '222 compound in an obviousness analysis, the prior art suggested a preference for halogen-containing compounds (the '222 compound did not contain a halogen), and the prior art identified a halogen-containing compound as particularly active. *Id.* at 904. Thus, the *Eli Lilly* court properly concluded that the '222 compound was not within the scope and content of the prior art because the prior art taught away from its selection for further development. *Id.*

The foregoing facts demonstrate that *Eli Lilly* is far from "identical" to the present case. Here, Defendants identified an abundance of teaching in the prior art that would have motivated one skilled in the art to recognize that Pirenperone should be developed, including biological data (*e.g.*, dopamine antagonism shown by the ATN test) and no EPS in humans. *See, e.g., Sections III.B.1. & III.B.2.b. of*

Defendants' FF/CL. Further, there was no teaching in the prior art that one should not pursue the development of Pirenperone, as even Janssen's Dr. Meltzer admitted that one skilled in the art in the early 1980s *would not have been deterred* from pursuing antipsychotic compounds under the combination dopamine and serotonin antagonism theory, *i.e.*, pursuing Pirenperone.[1] *See, e.g., DFF176.*[2]

The other cases cited by Janssen are similarly distinguishable. For example, in *Eli Lilly v. Teva* (*JFF/CL ¶ 141*), the defendant argued that it would have been obvious to use a chemical compound, fluoxetine, to treat premenstrual syndrome (PMS). (Fluoxetine was known to inhibit serotonin reuptake in the body, thereby lessening the serotonin deficiencies that cause depression and anxiety.) However, the *Teva* court found *no indication in the prior art* that a compound thought to affect serotonin reuptake was an effective treatment for PMS. Indeed, it found that the prior art *taught away* from this use, one prior art reference recognizing that "anti-depressants as a class were an incomplete treatment of PMS." *See Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 2004 WL 1724632, *26-27 (S.D. Ind., Jul. 29,

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[1] Even assuming Janssen's assertion that Pirenperone was only an anxiolytic is correct, Pirenperone would not have been ruled out for further development as an antipsychotic, as Janssen contends. This is because Jansssen's Dr. Meltzer admitted that one skilled in the art *would* prescribe an anxiolytic as an antipsychotic *(DFF196)* and thus would not rule out an axiolytic for further development as an antipsychotic. This was confirmed by Defendants' Dr. McMillen. *DFF196-DFF197.*

[2] A reference to paragraphs from Defendants' Findings of Fact and Conclusions of Law (July 26, 2006) will be referred to herein as DFF___ (facts) and DCL___ (conclusion of law), with the underlining being replaced by the appropriate paragraph number.

2004), *aff'd,* 2005 WL 1635262 (Fed. Cir., Jul. 13, 2005). The *Teva* court did not, as Janssen suggests, rule against the defendants on the basis that there were "multiple theories," concluding that the defendants had not relied on a "leading" theory. On the contrary, the court found that the prior art simply did not support fluoxetine as a compound that was within the scope and content of the prior art.

Here, the prior art not only recognized the viability of using Pirenperone under the dopamine/serotonin theory, Janssen's Dr. Meltzer admitted that one skilled in the art *would have been motivated to pursue antipsychotic compounds under this theory. See, e.g., DFF176. Eli Lilly v. Teva* is thus not relevant to, let alone dispositive of, the current issues.

Janssen also relies (*JFF/CL ¶ 77*) on a district court case *Eli Lilly & Co. v. Zenith Goldline Pharms.,* 2001 WL 1397304 (S.D. Ind., Oct. 29, 2001). This case is not relevant because the decision there focuses primarily on the failure of the defendant in that case to demonstrate a reasonable expectation that the asserted modification would produce a compound having the desired activity. *Id.* at *8-9. In contrast, Defendants here have identified prior art which confirms that the modification of Pirenperone would have been undertaken with a reasonable expectation of success, *i.e.*, the modification would have resulted in a compound having antipsychotic properties. *See, e.g., DFF134-DFF148.* Moreover, Janssen's use of this case in support of its allegation of hindsight also fails because, unlike defendant Zenith (*9), Defendants have identified reasons in the prior art which

would have made Pirenperone fall within the scope and content of the prior art——a candidate for development as an antipsychotic. *See Table (p. 2), supra; Sections III.B.1.and III.B.2.b. of Defendants' FF/CL.* Janssen's reliance (*JFF/CL ¶ 77*) on *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.* 417 F. Supp. 2d 341, 372 (S.D.N.Y. 2006) fails for the same reason. Again, Defendants here have identified reasons in the prior art which would have made Pirenperone a candidate for development as an antipsychotic, whereas the defendant in *Takeda* did not. *See, e.g., Sections III.B.1. and III.B.2.b. of Defendants' FF/CL.*

Janssen's reliance on *In re Baird* (*JFF/CL ¶ 76*) in support of its hindsight theory also fails to support its position. In *Baird*, the court rejected an obviousness assertion based on a single prior art reference that disclosed a chemical genus which encompassed at least 100 million species. Because the reference did not disclose the claimed species, and indeed taught away from the selection of components in the genus that would result in the claimed species, the obviousness rejection was overturned. *See In re Baird*, 16 F.3d 380, 382-83 (Fed. Cir. 1994).

Unlike the situation in *Baird*, Defendants' obviousness case does not rely on the selection of components within a genus encompassing hundreds of millions of compounds—it is based on a species already known to exist in the prior art—Pirenperone. *Baird* is thus inapplicable. Further, and even if one were to somehow apply *Baird* to the present case, Defendants have identified prior art references which clearly teach that Pirenperone would have been a species suitable

for development as an antipsychotic in the early 1980s. *See, e.g., Sections III.B.1. and III.B.2.b. of Defendants' FF/CL.*

III. THE ADMITTED WITHHOLDING FROM THE USPTO OF PIRENPERONE'S DOPAMINE ANTAGONISM UNDERCUTS JANSSEN'S REBUTTAL TO DEFENDANTS' *PRIMA FACIE* SHOWING OF OBVIOUSNESS

A. THERE CAN BE NO DISPUTE THAT THE PRESENCE (OR ABSENCE) OF A COMPOUND'S DOPAMINE ANTAGONISM WAS CRITICAL TO ALLOWANCE OF THE '663 PATENT

Defendants have established a *prima facie* case of obviousness relative to every claim of the '663 patent. Meeting their burden was eased by Janssen's admission that it withheld the dopamine antagonism of Pirenperone from the USPTO. *See, e.g., DFF231-DFF232; DFF236-DFF240; DCL9.*

There can be no serious dispute that dopamine antagonism was highly relevant to patentability during the '663 prosecution. Janssen argued during prosecution that "the animal test model used for evaluation of the claimed compounds"—*i.e.*, the combined apomorphine (APO)-, tryptamine (TRY)- and norepinephrine (NOR) test in rats ("the ATN test") and the apomorphine test in dogs ("APO-dog")—was "predictive of efficacy in treatment of a variety of psychotic diseases." *See DFF79; DFF87-DFF90; DTX-176, p. 4.* That which was relevant to patentability, remains relevant to today's obviousness inquiry.

B. THE APOMORPHINE ("A") COMPONENT OF THE ATN TEST INDICATES A COMPOUND'S DOPAMINE ANTAGONISM; THIS ANTAGONISM WAS ASSERTED BY JANSSEN TO BE PREDICTIVE OF ANTIPSYCHOTIC ACTIVITY

As explained in *DFF73-76*, each component of the ATN test indicates activity at a different neurotransmitter receptor. Janssen argued during prosecution that compounds that were serotonin antagonists only (shown by activity in the "T" part of the ATN test; *DFF75*), were not equated by the prior art with antipsychotic activity. *See DFF220-DFF228; DTX-176, pp. 4-6.* As explained at trial, the test using norepinephrine ("N" part of the ATN test) showed activity that was associated with side-effects. *See DFF312.* The "A" part of the ATN test shows a compound's dopamine antagonism. *See, e.g., DFF74; DFF88-DFF89; DFF220-DFF228.*

It was well known in the prior art in the early 1980s that dopamine activity was desired in an antipsychotic. For example, when discussing the ATN test and asked whether dopamine antagonism was considered in 1985 to be information that was important in determining whether a compound had antipsychotic activity, Janssen's Dr. Meltzer replied that "Dopamine antagonism was considered **extremely relevant**." *DFF86* (emphasis added).

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